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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,380	01/26/2004	Maurice M. Moloney	9369-292	4979
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BERESKIN AND PARR 40 KING STREET WEST BOX 401 TORONTO, ON M5H 3Y2 CANADA			EXAMINER RAGHU, GANAPATHIRAM	
			ART UNIT 1652	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Office Action Summary</p>	Application No. 10/763,380	Applicant(s) MOLONEY ET AL.	
	Examiner Ganapathirama Raghu	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 42-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 42-69 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 42-67, drawn to an isolated polynucleotide encoding a chimeric fusion polypeptide, vector, host cell and method of making polypeptide, classified in class 435, subclass 69.7.
- II. Claim 68, drawn to an animal transformed with the polynucleotide encoding chimeric fusion polypeptide, classified in class 800, subclass 13.
- III. Claim 69, drawn to an isolated chimeric fusion polypeptide, classified in class 530, subclass 350.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The polynucleotides of Invention I is related to the transgenic animal of Invention II by virtue of use of the polynucleotide in generating the transgenic animal. The DNA molecule has utility for the generation of transgenic animal. Although the DNA molecule and transgenic

Art Unit: 1652

animal are related, they are distinct inventions because they are physically and functionally distinct chemical entities, and the DNA may be used for processes other than the production of transgenic animal, such as in a nucleic acid hybridization assay.

The polynucleotides of Invention I is related to the polypeptide of Invention III by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the polypeptide in host cells. Although the DNA molecule and polypeptide are related, since the DNA encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the polypeptide, such as in a nucleic acid hybridization assay.

Invention II is unrelated to Invention III because the product of Invention II is a physically and functionally distinct chemical entity from the products of Invention III.

A search for more than one of Inventions I-III would be a burden on the Office for the following reasons.

The searches for any one invention are not required for and are not coextensive with the searches for any other invention, thereby creating an undue burden of search and examination. The results from a search of each of these inventions have different considerations with respect to the prior art. Burden lies not only in the search of U.S. patents, but also in the search for literature and foreign patents and in examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, written description and enablement.

Art Unit: 1652

The search of Invention I and II would not encompass a search for Invention III, which would include searching the prior art for teachings of the purified polypeptide. Conversely, a search for Inventions I and II, 435, subclass 69.7 and 800, subclass 13, would not encompass a search for Invention III, which would include searching class 530, subclass 350. Thus, a search of either Inventions I-II or III would not encompass a search for the other invention and searching both inventions would be a burden on the Office.

The search of Invention I would not encompass a search for any of Inventions II and III, as indicated by their distinct classification. Thus, a search for Invention I with any of Inventions II and III would be a burden on the Office.

Because the products of Inventions I-III are structurally and/or functionally distinct entities, a search for one said invention would not encompass a search for any other invention and searching all of Inventions I-III, or a subset thereof would be a burden on the Office.

These inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification. Furthermore, as explained above, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper. If Applicants should traverse the instant restriction based on an argument that the inventions or sub-inventions are not distinct, they should provide evidence as to why the skilled artisan would find any restricted inventions or sub-inventions obvious over their elected invention and sub-invention.

Species Election

Art Unit: 1652

This application contains claims directed to the following patentably distinct species of the claimed invention:

Group I, claims 48, 55, 56, 59, 64 and 66:

Claims 48 and 64: linker nucleic acid sequence is selected from the group consisting of:

- a) thrombin
- b) factor Xa
- c) collagenase chymosin
- d) viral protease

Claims 55 and 56 : heterologous polypeptide selected from the group consisting of:

- e) antibodies
- f) glycanase
- g) hormones
- h) proteases
- i) protease inhibitor
- j) seed storage proteins
- k) thrombin inhibitor
- l) hirudin
- m) an interleukin
- n) chymosin
- o) cystatin
- p) xylanase
- q) carp growth hormone

Art Unit: 1652

r) zein and

s) a collagenase

Claims 59 and 66 : oil body protein gene is selected from the group consisting of:

t) oleosin

u) caleosin

The species of Group I (claims 48, 55, 56, 59, 64 and 66) have either different structures or encode genes with different structures and are patentably distinct, searching for all the species would impose a serious search burden. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution from, i.e., linker nucleic acid sequence is selected from the group consisting of: from a) to d); heterologous polypeptide selected from the group consisting of: from e) to s) and oil body protein gene is selected from the group consisting of: from t) to u), on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **Group 1, claims 42-47, 49-54, 57-58, 60-63, 65 and 67** are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely

Art Unit: 1652

traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.


It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 4.30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
Art Unit 1652
June 01, 2007.


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